EXHIBIT C

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

In Re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation	Master File No. 2:12-MD-02327 MDL No. 2327
This document relates to all Wave 8 and subsequent wave cases as plaintiffs	Joseph Goodwin U.S. District Judge

Deposition of AHMET BEDESTANI, M.D., taken on Friday, September 21, 2018, in the conference room of Courtyard by Marriott, Two Galleria Boulevard, Metairie, Louisiana 70001, commencing at 11:52 a.m.

Reported by:
AURORA M. PERRIEN
CERTIFIED COURT REPORTER
REGISTERED PROFESSIONAL REPORTER

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**Reporter's Note: Exhibit Nos. 2 and 4 were retained by plaintiff's counsel.

A P P E A R A N C E S

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S T I P U L A T I O N

It is stipulated by and among Counsel that the deposition of AHMET BEDESTANI, M.D., is being taken under the Federal Rules of Civil Procedure for all purposes permitted under the law.

The formalities of reading and signing are waived.

The formalities of sealing, certification and filing are hereby waived. The party responsible for services of the discovery material shall retain the original.

* * * * *

Aurora M. Perrien, Certified Court Reporter, Registered Professional Reporter, in and for the State of Louisiana, officiated in administering the oath to the witness.

AHMET BEDESTANI, M.D.,
4228 Houma Boulevard, Suite 410A, Metairie, Louisiana 70006, after having been first duly sworn, testified on his oath as follows:

E X A M I N A T I O N

BY MR. JONES:

Q. Hey, Doctor. My name is Nate Jones. I'm from the law firm of Wagstaff & Cartmell. I think you already know this, but I represent the plaintiffs in the transvaginal mesh MDL that is headquartered in Charleston, West Virginia, and is ongoing.

So are you prepared today to answer some questions about the work that you performed in this case?

A. Yes, sir.

Q. And just briefly break it down to me what your understanding of your role is in this case.

A. I don't know how to answer that, really.

Q. You're sure?

A. My role -- I believe I was retained by defendant's law firms to answer questions regarding the accusations against certain products put into the marketplace by Ethicon, and to give information based on science, education,

experience.

Q. And is there one particular product that attorneys for Ethicon have asked you to look at specifically?

A. Prosima.

Q. Okay. So we're here today to talk bout Prosima and the work that you've done.

You've authored an -- what's called an expert report on the Prosima product; correct?

A. That is correct.

Q. Okay. And I'm assuming that you spent some time authoring that report of yours?

A. I did.

Q. Okay. And your counsel e-mailed me earlier a invoice detailing certain work that you performed.

Just to cut to the chase, is it fair for me and other attorneys to look at that invoice and rely on it for the amount of work that you performed in this case?

A. The -- there should be an invoice that was a preliminary invoice that is 58 hours, then there was another one for another 6 hours relating to that general report; so in total, 64.4 hours specifically devoted to the Prosima general

report. But I must add that that is a fraction of the time that I spent in that it -- I used this as an exercise to satisfy intellectual curiosity and to improve my understanding of certain concepts.

Q. If we combine the preliminary invoice, which totals to 58.1 hours, and the second invoice, that would total it up to 64.4 hours.

That's what we need to look at to determine the amount of time that you've invoiced for in this case. Fair?

A. That is fair.

Q. Okay.

A. Invoice time, 64 hours.

Q. Okay. Now on this invoice, I got to ask you a few questions about some of the language on here.

A. I don't have the invoice in --

Q. Okay.

A. -- front of me here.

MR. WALKER:

Here, we can -- we can look at it here. I have it on my screen; so just let us know what you're looking at.

BY MR. JONES:

Q. Yeah. The very -- the very -- towards the

very end, on Page 3 of 3, underneath Consulting, it says, "Preparation of Prosima" or Prosima, however we're going to roll in this depo, "Position and and supporting slides."

What's the Prosima position statement paper that you were working on?

A. Isn't that my report?

Q. That's my question.

A. That is my report.

Q. Okay. And then the supporting slides, what are you referring to there?

A. I believe -- I have it in -- in my hand.

MR. WALKER:

Let -- well, let me -- let me just interject to this point. They are references in attachment to his report. And a slide deck that -- that he used as sort of a foundation for his report should have been attached --

MR. JONES:

Okay.

MR. WALKER:

-- in the materials that y'all were served. I've got a copy for you here if you'd like that.

MR. JONES:

Yeah. Great.

MR. WALKER:

(Tenders document.)

BY MR. JONES:

Q. So you -- you put together -- you put together a report; correct? Yes?

A. I did -- I did put together a position statement. That position statement is in the form of a report that reflects my thoughts on Prosima.

Q. Okay. And then you also put together a PowerPoint slide presentation; correct?

A. That PowerPoint presentation is a run- -- is reflective of notes, images, information that I have gathered through the passage of time that has formulated my --

Q. I'm just asking --

A. -- thought process.

Q. -- whether you did it or not.

Did you --

A. Of course I did it.

Q. Did you put together the PowerPoint presentation?

A. That is 100 percent mine.

Q. Thanks. It's a lot of work.

A. It is a lot of work.

Q. Then a few of these other entries on the invoice, it says, "Research of chain breakdown in graft matrix."

Explain to me what you mean when you write on your billing invoice "Research of chain breakdown in graft matrix."

A. As I was reflecting on some of the accusations that were put forth or that I was made aware of in terms of how certain people believe mesh was reacting within the human body, specifically referencing papers accusing of oxidation, breakdown, etcetera. So when I dug deep into the actual papers, I had to re-educate myself, going back to organic chemistry, learning about isomers, learning about florescence testing, learning about electron scanning microscopy.

I would have to reflect upon my notes that I don't -- I don't think I have with me. But really trying to learn what florescence, transgravitent -- transgravonometric -- I'd have to pronounce it again. I'm certainly not an organic chemist, but I had to learn so I could make understanding of the papers and their rebuttal so that I can formulate my own

understanding, look at you and say I either believe it or I don't believe it.

Q. Sure. So the -- so underneath "Research of chain breakdown and graft matrix" and "Research into defending against accusations of" oxidate -- oxidate -- "oxidation of implants," talking about similar concepts there. Fair?

A. Polypropylene is a chain polymer. And then Prolene is a stereoisomer. So I had to really go back in that. And isotonic are all the carbon molecules and substituents on the same. So I would have to go back and go exactly into my notes to better delineate what I am trying to display to you. So I was really trying to say what was going on with the graft and was it really oxidation.

Q. So as far as your two entries in your billing invoice that relate to the "Research of chain breakdown and graft matrix" and "defending against accusations of oxidation of implants," you're -- you're talking about two similar concepts; correct?

A. Yes.

Q. Okay. All right. That's all the question was.

And then I assume you've come to the conclusion that polypropylene mesh does not degrade or oxidize inside of the human body. Fair?

A. I believe that Prolene, polypropylene is completely inert and does not do those things --

Q. Okay. And --

A. -- within the human body.

Q. Yeah. And in your research on that issue, you went out and looked at -- let me ask you.

Did you look at medical literature on the subject?

A. I did.

Q. And did you -- did you look at internal testing that Ethicon had done on the subject?

A. I -- I visited the papers by Abbott, Cabot [phonetic], if -- if -- I can't remember his name, and Clave.

Q. Clave?

A. Clave.

Q. Sure.

A. And then the accusations by Ostergard in his three in really trying to understand what was going on, and then really going back to Boyd's -- really going back to Boyd's Organic Chemistry

textbook, which was mine.

So really just trying to once again understand what all of this terminology was. I do -- I think I billed these -- the company 7 hours, but I could definitely tell you there was far more time spent just trying to understand these concepts and I didn't feel that it was appropriate to bill a company to --

Q. Yeah. Yeah. Yeah.

A. -- educate myself.

Q. Got it. And I'm not trying to be rude and cut you off, but I mean, if I ask you a question, I just want the answer to the question. I mean, you'll get it. You'll -- you'll get it. And I know it's like -- we're human beings. We try to have a conversation, and there will probably be some topics where you and I both will start getting into a conversation mode. But for now, this -- this -- these are like housecleaning issues; so --

A. Okay.

Q. -- I'm just firing like simple questions --

A. Okay.

Q. -- that I just want answers to.

So the question was -- you looked at what you looked at in -- in researching the issue of degradation or oxidation of polypropylene mesh implants inside of a woman's body. And I asked you if you looked at medical literature, and you said yes. And then I asked you if you looked at any Ethicon testing that the company had done on the subject. And so that's the question.

Did you look at any testing that Ethicon specifically had done on the subject?

A. I would have to reference my -- I think I -- in that huge binder there's over a hundred some odd papers, and there's ancillary material. If that -- if Ethicon material was there, I'm sure that I looked at it.

Q. Okay. And as far as -- we're talking about the reliance list of materials?

A. Yes.

Q. So let me -- let me shortcut this.

If an item is listed on your reliance list, it means that you looked at it at one point in time before preparing your report; correct?

A. Completely. Yes.

Q. Thank you.

And that means we can -- if -- if one of

these cases goes to trial and you're called to testify, we can, when you're up on the stand, look at that reliance list and we can pull out the document, show it to you, and say, Doctor, according to your reliance list, you looked at this prior to authoring your report -- I'm going to give you an opportunity to look at it again because it's probably been a second since you looked at it. But then you'll answer questions about it. Fair?

A. That is correct.

Q. Okay.

MR. WALKER:

Nate, are you done with this invoice?

MR. JONES:

Yeah.

MR. WALKER:

Okay. And you -- you may or may not ask about this, but let me just go ahead and state. I brought a flash drive that has electronic copies of all of the reliance material --

MR. JONES:

Yeah.

MR. WALKER:

-- that's contained. So if you want this --

MR. JONES:

Yeah. I want it.

MR. WALKER:

-- we do have it for you.

MR. JONES:

Awesome. Thank you.

MR. WALKER:

(Tenders document.)

MR. JONES:

We'll mark that invoice that we have -- if we can get the other one, please, or at some point in the future, would be --

MR. WALKER:

Yes.

MR. JONES:

-- be great. And we'll mark those for the record as Exhibit 1.

(Exhibit No. 1 was marked for identification and attached hereto.)

MR. JONES:

We'll mark this flash drive as Exhibit 2.

(Exhibit No. 2 was marked for

identification and attached hereto.)

MR. JONES:

That's it for now. Oh. And we'll go ahead and mark an electronic copy, which I'll send you, of his report and PowerPoint stuff as Exhibit 3.

(Exhibit No. 3 was marked for identification and attached hereto.)

BY MR. JONES:

Q. All right, Doctor. Let's switch gears. This is the section of the deposition where I ask you a whole bunch of questions about work that you've done for Ethicon before this case, before expert work, before this case ever existed. So I'm going to ask you questions about work you ever did for Ethicon, if you ever did work for any other mesh companies, and ask you about your -- your background a little bit.

So prior to performing work as an expert in this case revolving around the Prosima product, had you ever acted as a paid physician consultant for Ethicon?

A. Yes.

Q. Okay. Let's -- give me the breakdown of -- when did you first start acting as a paid

physician consultant for Ethicon?

A. 2010 would be a -- I think a good start point.

Q. Okay. And what would -- what did your consulting responsibilities entail in 2010?

A. Speaking about -- speaking to my thought process of the Prosima itself, graft augmentation, specifically Prolene, polypropylene augmentation of transvaginal reconstructive procedures to address pelvic organ prolapse, symptomatic.

Q. Fair to say in 2010 your consulting work for Ethicon consisted of work revolving around the Prosima product and other graft augmentation procedures for pelvic organ prolapse?

A. My main focus was specifically to provide professional-level education on behalf of Prosima. This involved preceptorship. This involved anatomical dissection, displaying that anatomical dissection.

Q. And in your work in 2010, your consulting work, would have primarily revolved around the Prosima product -- fair -- for Ethicon?

A. For Ethicon, only Ethicon. Prosima, only Prosima.

Q. Okay. Did you do any other work as a paid

physician consultant for any companies that market transvaginal mesh devices that aren't named Ethicon?

A. Absolutely no. I was paid to man a cadaveric lab while a fellow, and that's because my bosses said, Show up, and I did --

Q. Right.

A. -- and I collected -- I believe it was either 500 or $800. And that would be between 2007 and 2010. I -- I don't -- you would -- you could -- I -- I don't know exactly when. It was on behalf of Pinnacle. So whenever Pinnacle hit the market, it would be around that time.

Q. Got it.

As far as your consulting work, you -- other than the one event that we just described that you were required to attend, your consulting work was solely with Ethicon as it relates to transvaginal mesh; correct?

A. Solely with Ethicon as it relates with Prosima.

Q. Okay. Why is it that you only worked for Ethicon?

A. I believed in the -- the concept of mesh augmentation. But more importantly, I was

fascinated, not intrigued, fascinated by the vaginal support device, which is a component only of Prosima.

Q. The -- the Prosima uses the vaginal support device, or -- or VSD, which is unique to all other transvaginal mesh POP kits ever on the market; correct?

A. Excuse me? I -- you have to repeat that for me.

Q. The -- the Prosima uses the VSD, or vaginal support device, mechanism; correct?

A. That is correct.

Q. And the design of the Prosima, which includes the VSD device, is unique to any other transvaginal mesh POP kit ever marketed in the United States. Fair?

A. Absolutely no.

The vaginal support device was only involved with Prosima. There was no other splinting-type device that I was aware of for any other marketed transvaginal mesh kit: Apogee, Perigee, Elevate, Pinnacle, Uphold. I can't keep them straight.

Q. Sure. There's a bunch.

But as far as the splinting -- the splint

device, that was unique to the Prosima; correct?

A. Yes.

Q. Okay. All right. None of -- I'm not aware of it either.

But there's -- there's no other transvaginal mesh product that you're aware of that uses the type of design that Prosima does; correct?

A. That is correct, sir.

Q. And that's why you're fascinated, I'm -- I'm assuming -- let me ask.

Is that one of the reasons why you were fascinated by the Prosima back in 2010? It was different --

A. Way before.

Q. -- right? Oh. Way before?

A. Way before, I always felt that precision of application of graft with vector molding, intrinsic or extrinsic pressure, was the key. Basically I felt that Ethicon, when they introduced me to the vaginal support device, gave me what I had been looking for. I felt that that would solve a lot of problems, and I once again was fascinated by this concept.

Q. And the concept was invented by a

Australian doctor; correct?

A. I believe it was Marcus Carey, to be specific.

Q. Yeah. He's Australian; right?

A. Yes.

Q. Okay. And do you know when Prosima was launched in the United States?

A. I remember attending some type of event in Colorado where they were getting ready to roll it out. And I say that because I would have to look back at my travel logs. It's either going to be 2009 or beginning of 2010.

Q. That brings up a good point.

Was this rollout event that you attended in 2009 or 2010 an event sponsored by Ethicon?

A. I believe it was.

Q. I'm assuming, dating back to 2009 or 2010, that you've attended multiple events sponsored by Ethicon in your role as a consulting physician?

A. From 2009 to -- yeah.

Q. To -- to current? Okay.

A. I -- I attended many such events. Many such events not only sponsored by Ethicon but all of the companies at the time.

Q. Good.

And have you -- have you -- has Ethicon paid for you to travel to their headquarters?

A. I did go to their headquarters, but that's when I went to see my family. I did. Because we are -- we live in Hamilton, New Jersey, which is not that far from East Brunswick or Somerville.

Q. Sure.

Do any other events or trips stand out to you in the last 8 or 9 years that you attended where Ethicon either sponsored the event or paid for you to travel there?

A. Many wonderful memories come back from labs that were hosted or put forth by Ethicon: Chicago, Florida. I would have to look back at the travel log. Many.

But I do know this: It was through all of these labs that I was able to further dissect and further advance my knowledge in pelvic anatomy. Because I can tell you this: Through that company I was able to study over 26 cadavers. So usually it was four cadavers per an event. Four into 26 -- let's round up. Say I missed two. So at least seven events.

Q. All right. So 2010, you're a consultant for Ethicon.

2011, are you a consultant for Ethicon?

A. I think so.

Q. 2012, are you still consulting with Ethicon?

A. No. I'm not.

Q. Okay. What -- why did you stop acting as a physician consultant in 2012 for Ethicon?

A. I think I -- I actually transitioned out of one position and then took some time to decide in what direction my career was going to go; so I felt that was an important part. And it -- that was -- it was at that point that I passed my general obstetrics and gynecology boards, two thousand and -- I think it's right here. Two -- November of 2011. And then I started putting together my practice at East Jefferson General Hospital, and that took some time to really get off the ground. So I was really devoted to that.

Q. Okay. Did Ethicon between the years of 2012 to 2016 ever reach out to you to ask you if you would act as a paid physician consultant for them again?

A. No.

Q. Now November of 2011 is when you first passed your general OB-Gyn boards; is that

correct?

A. That is correct.

Q. And you finished -- finished your fellowship training in June of 2010; correct?

A. That is correct.

Q. And then you talked about starting your practice at East Jefferson; correct?

A. Yes. I left my -- my previous -- where I did my fellowship, I stayed on, and I felt that it was time to move on.

Q. Sure.

A. And so I think that was a period of transition.

Q. So sometime in late 2010 you begin practicing as a full-time physician; correct?

A. I was a fellow from 2007 to 2010. And then I joined as an assistant professor, and so I was -- at that point we transitioned from fellow to attending. That is correct.

Q. Okay. And then at some point in 2011 you start your practice at East Jefferson; correct?

A. We started I think in May of 2012. It took a while to get started. It should be then. Yeah. May of 2012.

Q. When's the last time that you used the

Prosima device in a patient?

A. I -- I think probably in 2011. Probably.

Q. Okay. When is the first time you used the Prosima device on a patient?

A. As soon as I could probably get my hands on it; so probably somewhere in 2009 or 2010.

Q. Fair to say the first time that you would have used the Prosima device would have been shortly after it was first marketed in the United States?

A. As soon as I could obtain the device. Yes. Whatever that time period is.

Q. How many total Prosima devices did you implant in patients?

A. That would be a -- that would have to be a range.

Q. Give me a range.

A. Probably more than 40, less than a hundred.

Q. Now in the course of your review in -- in -- in educating yourself about issues that were relevant to the Prosima device, you're aware that the launch of the Prosima device was delayed several times by Ethicon; correct?

A. I didn't know that at the time where --

when it first was presented to me. On further study, I do know that it was delayed for some time, but I felt that that was a good thing in the sense that they wanted to actually have good Level 1 data.

Q. You became -- any time I say something that's off-base, correct me if I'm wrong.

When you -- when you were a practicing physician in 2009 and 2010 and started using the Prosima device, you had no knowledge at that time that there was delays in the launching of the device made by Ethicon; correct?

A. That is correct.

Q. At some point in your review of materials and in authoring and in -- in authoring your expert report in this case on the Prosima device, you -- you became aware that there were several delays of the launch of the Prosima device made by Ethicon; correct?

A. That is correct.

Q. And you would have became educated in that subject when you reviewed internal documents supplied to you from attorneys who represent Ethicon. Fair?

A. That is correct.

Q. Okay. And in fairness, the only way that a physician could have known that there were multiple delays in the launch of the Prosima device would be to have access to Ethicon's internal documents; correct?

MR. WALKER:

Object to form.

BY MR. JONES:

Q. That's a bad question. Let me ask in a more targeted question.

One way a physician would become aware of the multiple -- multiple delays in the launch of the Prosima device made by Ethicon would be to have access to their internal documents; correct?

A. No. Because if a company says that Product X is coming September 2008 and you're waiting for it and it doesn't show up, then that keys you off there's a problem. So I think finding out the developmental timeline of a product, I don't know if that's really germane to the issue at the time.

Q. You reviewed -- I mean, the -- the internal documents are -- to me are interesting, actually, in this -- with this device. Sometimes they're not that interesting. But with Prosima,

they are definitely interesting. There's some that really stand out.

And -- and I'm sure you reviewed documents where employees at Ethicon are disappointed with some of the initial safety data that came back prior to the launch of the Prosima device; correct?

MR. WALKER:

Object to form.

THE WITNESS:

I don't remember any type of information standing out regarding safety data, none -- nothing regarding safety.

BY MR. JONES:

Q. You reviewed documents where Ethicon -- employees at Ethicon were concerned about the performance data of Prosima prior to its launch; correct?

A. Please define --

Q. Meaning whether -- meaning whether it worked or not.

A. Of performance --

Q. Sure.

A. -- in terms of --

Q. Efficacy.

A. Okay. That's a good word.

I do believe that the concept of success still eludes pelvic floor surgeons. I think we've seen that in Barber's paper. And I think understanding what Prosima envisioned in terms of a tension-free placement -- and I always liked that word "tension-free."

Q. It sounds nice.

A. It sounds nice.

Q. Endearing. All right. Here's the question, because I don't think you answered it. It's a simple -- whether you saw documents or not. I'm guessing you did, but I got to ask.

Did you review documents where employees at Ethicon were concerned about efficacy data associated with the Prosima device prior to the device being launched onto the market in the United States?

MR. WALKER:

Object to form.

THE WITNESS:

I saw a lot of correspondence in the form of e-mail that was difficult to delineate because it was -- there was such a substantial volume. And I do recall

reading some people making mention that -- in terms of how they were going to report the data, I think there was ongoing debate about that. But at no time did I see anything regarding safety.

BY MR. JONES:

Q. Let me ask it this way: You know based on your review of the documents that there was a -- there was a level of concern inside the company with multiple employees at Ethicon, including medical directors, about the performance or efficacy of the Prosima device before it was ever launched onto the market? You know that -- right -- based on your review of the documents in this case?

MR. WALKER:

Object to form.

THE WITNESS:

In my review of probably gigabytes of information, I recall people being concerned about 83 percent versus 94 percent efficacy and how one study was going to shoot for 90 percent and maybe they did not achieve that so there was ongoing debate about that. But I don't

know who was providing the data, where was the data coming from.

BY MR. JONES:

Q. You don't know who was providing that data?

A. In terms of the actual surgeons --

Q. Okay.

A. -- who were -- who was producing it --

Q. Well, one of the surgeons --

A. -- what was the skill set --

Q. One of the surgeons was Marcus Carey; right?

A. That is correct.

Q. So if there is going to be any surgeon that has a skill set on a particular device, it probably will be the person that invented that device and is a internationally respected surgeon; correct?

A. Until Prosima, I had never heard of Marcus Carey. But I was intrigued to meet him, and I think I met him once.

Q. Well, let me ask you this: Have you ever invented a transvaginal mesh device?

A. No.

Q. Have you ever invented a medical device?

A. I wanted to put standard pessaries in people after we floated mesh into people, and I was denied that.

Q. Yeah.

A. I . . .

Q. So you haven't successfully invented --

A. I have -- I have --

Q. -- a medical device? Okay.

A. -- failed to do that.

Q. You failed. Your words, not mine.

But you failed --

A. I failed --

Q. All right.

A. I failed --

Q. So you realize how difficult it is, and so you respect Marcus Carey in that regard; correct?

A. I think Marcus Carey is only one player in a huge team effort to bring something from concept to actually placing it in a human being in the United States of America. I think marketing is a component of science, of --

Q. What about --

A. -- of --

Q. -- Marcus [sic] Slack?

A. I am sure -- the name sounds familiar. I

would have to look at what Marcus Slack's contribution is. I can't remember something.

Q. What about Dr. Helen [sic] Zyczynski?

A. I know Dr. Helen Zyczynski all the way from the fellowship application trial. She didn't hire me as a fellow at the University of Pittsburgh. She's a past president of AUGS. I know her by reputation. And I know that she was one of the lead investigators of the Prosima trial. And I really came to -- I forgave her for not taking me as a fellow when she said these words at one of these education events. She goes: Do not be led astray by this product. It requires great sophistication to perform. And I -- at that moment, my level of respect for Dr. Zyczynski went through the roof. So I know who that one is --

Q. Well, you --

A. -- because she had an effect on me.

Q. You respect her?

A. Right.

Q. So earlier you were questioning these -- you were bringing into question the skill set of some of these surgeons that were providing the data.

You're not going to question

Dr. Zyczynski's skill set?

A. She's at an academic institution with medical students and fellows. If she said that she did a Prosima and that -- whatever her operation rate, whatever she told me, I would believe that. So what I need to know: who was doing the actual operating at her facility.

Q. And have you --

A. Mind you, I don't agree with everything that Dr. Zyczynski does blindfolded. She does not even do urodynamics. She does not do interval slings on her . . . So everything that I do -- when I say that I know someone or I respect their work, everything is taken in a spectrum. You've taken the -- their whole production of work.

Q. Sure. Have you seen -- I'm assuming that you've seen the Zyczynski study?

A. Yes.

Q. Okay. Have you seen -- has -- have attorneys for Ethicon provided you the underlying data for that study?

A. I probably have perused it as well as the prof ed slides of which I think there were 50 or 60 beautiful slick PowerPoint presentations of which I used that as the basis of talks.

Q. Have you ever taken the data as it's written and recorded in an article and compared it to the underlying data that attorneys for Ethicon have supplied to you?

A. Did I sit down and refigure the statistics? I --

Q. Or just compared them. I don't need you to refigure them. I just want you to look at them as they're reported in the article and as they're reported coming in from the data centers to Ethicon.

A. I would have -- I would have to revisit that issue --

Q. Okay.

A. -- and I'm happy to do so.

Q. Perfect.

And you would -- since you haven't done it yet, you will at least admit that if there are significant differences between the way the data is presented and recorded in the article as it comes in from the data centers, that that could be a potentially misleading issue; correct?

MR. WALKER:

Object to form.

THE WITNESS:

I think it is important to review the data in a totality. You -- it's not just one data point, but it's many data points. So if you ask me and you put all of the papers right in front of me, I will be more than happy to review it and then right there on the spot state my findings.

BY MR. JONES:

Q. You don't want people changing the data from the point of time when it comes in from the surgeons' data center from the point to where it gets published in an article; correct? That's generally a bad thing; right?

A. Changing --

MR. WALKER:

Object to form.

THE WITNESS:

-- values in terms of what happened. So if they say -- if the patient comes in -- and I have to use an example. I'm sorry. I'm not trying to make this difficult. If the patient comes in and AA six weeks post-op is plus-one and someone reports that as minus-one, that data point right there, if you capture that lie, that

is unethical. That is unethical.

BY MR. JONES:

Q. It's unethical to take data that comes into you as a company and change it to present it in a more positive light in a medical journal; correct?

A. Are you --

MR. WALKER:

Object to form.

THE WITNESS:

-- accusing people in a totality of massaging data?

BY MR. JONES:

Q. Well, I'm not accusing anyone of anything. All I'm asking is questions.

When you look at the data as it's published compared to as it came in from the data centers, which you haven't done -- when you compare those, they're different. And I think once you do do that, then it could raise some questions for you from an ethical standpoint.

A. So --

MR. WALKER:

Object to form.

THE WITNESS:

-- if I'm understanding properly, if individual site investigators truly report the correct data to the company and then the company changes the actual data points, that -- so that the AA which is reported as plus-one, if someone changed that at the company level, that would of course be improper.

BY MR. JONES:

Q. Prosima -- Prosima uses Prolene -- or Prosima uses Ethicon Prolene mesh; correct?

A. Ethicon use -- I mean -- excuse me. Prosima uses Ethicon's Gynemesh PS, which is Prolene -- Prolene -- polypropylene soft. I think that's what the "PS" stands for, Prolene soft.

Q. Prosima uses Ethicon's Prolene soft mesh; correct?

A. That is correct. Gynemesh PS.

Q. Yeah.

The stiffness value of transvaginal mesh, especially when used in pelvic organ prolapse repair, is one important mesh characteristic in assessing -- in assessing the performance and safety of transvaginal mesh; correct?

A. One of many factors.

Q. Stiffness is one of many factors important in assessing the safety of transvaginal mesh; correct?

A. One of many. That is correct.

Q. Stiffness matters when it comes to the safety of transvaginal mesh; correct? I mean, there's medical journals out there that talk about it; right?

A. Of course you're --

Q. All right.

A. -- not going to place something as stiff as a 2-by-4 in someone's anatomy. Stiffness, pliability, porosity.

Q. Density?

A. Correct.

Q. So -- and there's -- and you know this --

A. Burst strength and --

Q. Burst strength --

A. All of it.

Q. -- tensile strength, those things probably don't matter as much just because, you know those are tests for carpenters. But -- not really, in my mind, pelvic floor surgeons. But --

A. I think people at the University of Pittsburgh, Moalli specifically --

Q. Sure.

A. -- has made a career of really trying to figure out a mechanism in which to delineate some of these factors. But I don't think that they have succeeded in producing a proper human model. I might be incorrect by saying that. I don't know. I remember some monkeys got slaughtered, and I didn't agree with the -- the way that that study was done. And I'm not trying to be funny.

Q. No. I know.

A. I'm not trying to be funny.

Q. No.

A. I did not -- I did not like that study when it was presented at the podium. So --

Q. Yeah. It's interesting.

A. -- I -- I think -- so we have a lot of factors in the behavior of mesh, which you said. And so you don't think that I'm trying to be obstinate, you are correct. Stiffness is very important. Porosity is very important, weight, all of that.

Q. This is going to be one of those times where we both -- we just kind of have a conversation back and forth.

You're familiar with the work done at the

University of Pittsburgh led by Dr. Pam Moalli, where a group of surgeons and researchers -- researchers have focused in on the stiffness of transvaginal mesh and how that relates to patient safety; correct?

A. Yes. Her and her team, not Dr. Moalli only. She has --

Q. Right.

A. -- biomedical engineers.

Q. There's a team of surgeons and researchers working on stiffness of transvaginal mesh and the safety of transvaginal mesh at University of Pittsburgh; correct?

A. And all other parameters, that is correct.

Q. And they published several articles that specifically deal with the stiffness of mesh; correct? One of -- correct?

A. That is correct.

Q. One of which you referenced earlier that involved the sacrificing of monkeys; correct?

A. That is correct.

Q. And you're aware that -- yeah. I'll leave it at that.

So -- and you're aware of what they've done in some of those studies, is they've taken

several different transvaginal mesh product devices that have been marketed on -- in the United States and compared the stiffness values of them; correct?

A. They didn't use the kits. They used the mesh in the kits. That is correct. All of the different trade names, which I cannot keep straight.

Q. I can't either.

A. I would have -- I would have to use a graph --

Q. Yeah.

A. -- and I would have to look at the paper. But you are correct. All -- all of that data -- most of that data has been that source or that academic center.

Q. And to -- to -- I'm sure people love this, when people in a conference room do this to their years of research and work.

But to oversimplify their work, they -- they have general -- generally concluded that the stiffer the mesh is, the more safety risk it poses to women in the realm of pelvic organ prolapse; correct?

MR. WALKER:

Object to form.

THE WITNESS:

I can't answer that with a yes or no. I need to explain something. I think stiffness, which is only one of the parameters, is a spectrum. And I do not know exactly what the correct spectrum is to this day in 2018. I don't know what the perfect value is for all of these --

BY MR. JONES:

Q. Yeah. I'm not --

A. -- parameters.

Q. -- asking what you think. I'm asking what they think, based on your review of those articles. And so their over -- overgeneralized conclusion as it relates to stiffness of transvaginal mesh is the stiffer the transvaginal mesh product is, the more safety risk it poses to the patient; correct?

A. I think we would --

Q. That's generally what --

A. I -- I think that --

Q. -- they're saying?

A. -- I -- we would have to go back to each paper and look. But they usually end the papers

by saying it has to be an area of ongoing research.

Q. That's what every paper says; right?

A. I didn't -- I can't attest to every paper in the world.

Q. Right. Right.

A. But . . .

Q. I'm asking you generally, though.

From a general standpoint, their viewpoint is the stiffer the mesh, the less state -- the less safe the mesh; correct?

MR. WALKER:

Object to form.

THE WITNESS:

I don't -- I don't know if I can say that. I think that it -- it represents a different value that has to take -- be taken into account.

BY MR. JONES:

Q. All right. I guess we'll just disagree on what the University of Pittsburgh has concluded in their articles.

You've reviewed internal documents from Ethicon that -- that discuss the stiffness of the mesh used in Prosima; correct?

A. There is documentation on the review of all this data regarding that weight -- that weight or stiffness question. That is correct.

Q. Okay. I'm going to show you one document. I'm going to give you however much time to a reasonable standard that you want to look at it, and then I'm going to ask you maybe five questions about it.

MR. JONES:

And I'll e-mail it to the court reporter. I'll mark it as Exhibit 3 -- 3 -- 4.

COURT REPORTER:

(Indicating.)

MR. JONES:

Thank you. Exhibit 4.

(Exhibit No. 4 was marked for identification and attached hereto.)

BY MR. JONES:

Q. It is titled FWD: Project Gynemesh Vypro PD00, backslash, 3. It's an e-mail dated April 18th, 2001. And it attaches to the e-mail a PowerPoint presentation, which you're familiar with, Doctor, about Vypro mesh. And it discusses some things about the mesh used in Prosima that I

want to ask you about. So -- so questions I'm going to ask you about, on the very last page, 28 of 28. So skip there. But you can skip forward, skip back. Have at it.

A. Option 1, Option 2, Option 3 . . . Project.

MR. WALKER:

Sorry.

THE WITNESS:

That's okay.

MR. WALKER:

Go back down.

THE WITNESS:

So Gynemesh Vypro, which we know is --

BY MR. JONES:

Q. I haven't asked you any questions yet. Just take your time to --

A. Oh.

Q. -- look at it, and then I'll ask you questions. If you're just reading out loud, what the documents says --

A. Polypropylene --

Q. -- that's my bad. But . . .

A. Yeah.

MR. WALKER:

Yeah. Just take a -- take a second to look at this and then wait for his question.

THE WITNESS:

What does "VOC" mean?

MR. JONES:

Voice of customer. That -- that's you.

MR. WALKER:

Hang on. Let's go to the top. 2001 . . . Sorry. Let's go.

THE WITNESS:

Huh?

MR. WALKER:

All right. Are you ready?

THE WITNESS:

I'm ready.

BY MR. JONES:

Q. You're ready? All right. You and your attorney have had an opportunity to look at that document; correct?

A. My attorney?

Q. You --

A. I don't think -- I can't say that. The -- the -- the representative of the company. But

yeah, we both looked at it. That is correct.

Q. That's a good point. I'll -- I'll -- I'll rephrase the question if that's important to you, because it seems like it is.

You've had an opportunity to look at that document; correct, Doctor?

A. I -- you just gave it to me to take a look, and I look -- seen it. Yes.

Q. Okay. Have you ever seen that document before?

A. No.

Q. First time you've seen that document; correct?

A. This is the first time that I am seeing something regarding Gynemesh Vypro.

Q. And did I state correctly earlier when I said it was an e-mail dated from 2001?

A. I didn't have the smarts to scale up. The Ethicon attorney did. So this is --

Q. Yeah.

A. -- from 2001. That is correct.

Q. See if the Ethicon attorney does?

A. That's . . .

Q. All right. So the document's dated from 2001; correct?

A. Uh-huh.
Q. Okay. And the e-mail that's dated 2001 attaches a PowerPoint, which you have now had an opportunity to look at. And on the last page of the PowerPoint, it -- it makes some recommendations and statements as it relates to Vypro mesh and as it relates to Prolene soft mesh; correct?
A. That is correct.
Q. Okay. And in that chart it talks about stiffness; correct?
A. Disadvantages. It says VOC.
Q. VOC, voice of customer?
A. Voice of customer --
Q. Okay.
A. -- which I asked and you were kind enough to tell me. It says, Too stiff for use in vaginal tissues.
Q. Too stiff for vaginal -- for use in vaginal tissues is listed under the Prolene soft mesh; correct?
A. Yes. It is.
Q. Okay. And then next it says, Team recommendation: Do not pursue; correct?
A. Well, it says, risks, cost, timing.

Because this is a three-by-one, -two, -three, -four, -five, -six --

Q. Okay.

A. -- -seven . . . So it's a substantial chart. And at the end it says, Team recommendation: Do not pursue. But it says the same thing for Option 2. And then Option 3 is -- and I knew you didn't ask me that. But this is a point. It says, Pursue as a second generation.

Q. Yeah.

A. So this is 2001.

Q. So we're talking in 2001, and we're looking at a PowerPoint presentation inside the company; correct?

A. (Nods head.)

Q. Do you know who -- let me ask you about some of the -- the engineers, mesh employees, and researchers at Ethicon that were involved in -- in this PowerPoint.

Do you know who Dr. Holst is?

A. No. I do not.

Q. Do you know who Dr. Brigitte Hellhammer is?

A. No. But I would --

Q. Do you know --

A. -- remember that name.

Q. It's a pretty memorable -- memorable name; right?

A. Yes.

Q. So if you've seen it before, you'd remember it; right?

A. That is correct.

Q. How about -- what about Laura Angelini?

A. Laura Angeline?

Q. Angelini.

A. Angelini? Oh. It -- the name sounds familiar, but I can't put a face to it.

Q. What about Dr. David Robinson?

A. Don't know him.

Q. What about Dr. Aaron Kirkemo?

A. I worked with Aaron Kirkemo, taking apart four or five of those cadavers. I learned a lot from him. I know him, and he reported to the big boss, the big, big boss, Pete Anewel [phonetic]. That is correct.

Q. Do you consider -- based on your understanding, Pete Anewel is the big boss?

A. I think he was like -- I thought it was wonderful -- you know, talking to him was interesting. He was trained in Belgium.

Q. Sure.

A. He had an interesting thing. And I think he had a title at that time. Remember, I'm just a fellow.

Q. I got it. Yeah.

You're just a fellow --

A. In --

Q. -- in Louisiana?

A. In Louisiana.

Q. Right.

A. This guy's like --

Q. You're a little --

A. -- a PhD and a doctor, I think.

Q. Right. And he's -- and he has a good --

A. And --

Q. -- a good presence?

A. I don't care about that. But he did have --

Q. You don't care about that?

A. I think he had the title known as worldwide director.

Q. Worldwide medical director. Yeah. It sounds big. It sounds important.

Aaron Kirkemo, you respect him, though; right? Correct?

A. I thought he was knowledgeable. I appreciated how he dissected a pelvis; so I -- I know that he had skill.

Q. Okay.

A. Or -- cadavers are dead. He has knowledge.

Q. Right.

A. So he had knowledge, and I respect knowledge.

Q. Yeah.

What about Dr. Thomas Barpul [phonetic]?

A. I don't know him.

Q. What about -- did you ever look at -- and this would stand out if you did. Did you ever look at a consulting -- I think it's from 2011. Ethicon pays a big fancy company overseas to do kind of a consulting project or auditing project. They're called the PA Consulting Group.

Did you ever see -- it would have been a -- in your review of documents that attorney for Ethicon may have provided you or not, did -- did you ever see documents from PA Consulting Group that discussed degradation of Ethicon's mesh products or oxidation of Ethicon's mesh products?

A. I would have to look, because I didn't see

the substantial amount of information from the law firm that represents --

Q. Sure.

A. -- Ethicon. So I would have to look back at everything.

Q. Nothing stands out --

A. But nothing stands out about a PA Consulting because I would have -- I would -- if I had came -- because I'm curious. I would want to know what --

Q. Right.

A. -- PA Consulting is and who is it.

Q. Right. If -- if you saw a lengthy PowerPoint presentation similar to the one that you did for Prosima that someone puts together and -- and -- and, you know, there's doctors involved, they interview company employees, and it makes some conclusions like mesh degrades, that would stand out to you? Because you would want to do additional research into that; right?

MR. WALKER:

Object to form.

THE WITNESS:

When I came across Clave and papers -- I'm just using Clave and then the Cabot.

I definitely went above and beyond to answer that question. So if I came across a document that said this, I would definitely investigate it. And I think you believe me, that I would.

BY MR. JONES:

Q. I -- I totally believe you. And that tells me that you probably more likely than not didn't see that document. Because --

A. I --

Q. -- we would have -- we -- I feel like we would have had a conversation about it just now and the work that you would have done. We could have had -- you know, like you said, you would have been like: Who the heck is this PA Consulting Group? You would have reviewed any papers they looked at. I -- I just have that feeling we would have had a conversation about it.

So it tells me -- and correct me if I'm wrong -- that more likely than not that's not one of the documents that attorneys for Ethicon provided you in reviewing materials; correct?

A. I don't remember seeing anything from PA.

Q. Do you remember -- we talked about the unfortunate issue of sacrificing monkeys earlier.

But -- and -- and so it made me think of this earlier, and I don't know -- think I asked you about it.

But did you review materials from attorneys from Ethicon that relate to internal testing they did on dogs? It's commonly referred to as the 7-year, 5-year, and 10-year dog study. But Ethicon got beagles. They went out and found beagles, nice beagles, and they implanted the dogs with Prolene. Did you review those documents?

A. I did not see anything relating to dog labs.

Q. Okay.

A. If you've ever read the Guyton physiology definitive textbook for most medical students, the whole book is representative of a dog slaughterhouse. Most of the studies were done on dogs. Prolene suture, because of the cardiac indication -- I'm sure that many animals hopefully have furthered human --

Q. Yeah.

A. -- well-being with their sacrifice. I don't know what to say to that.

Q. Yeah. Unfortunately the dogs didn't make it in that study. They didn't even make it to the

end of the study. All right.

MR. WALKER:

And that -- that was not Ethicon's fault, just for the record.

MR. JONES:

Okay. All right. Ethicon doesn't kill dogs. All right.

BY MR. JONES:

Q. All right. Let's go back to some of this consulting work stuff. Because I should have asked you some questions on it that I didn't earlier. And you tried to lead me in the right direction, and I just didn't follow up.

Now in 2016, did you do consultant work for Boston Scientific?

A. No.

Q. Okay.

A. In 2016 I did not do any type of consulting work for Boston Scientific.

Q. Okay. Did -- did -- did you perform consultant work for Boston Scientific at any point in your career as a physician?

A. As I alluded --

Q. Other than the one --

A. No.

Q. -- required -- no.
Coloplast. There's some entries of interactions --
A. No.
Q. -- between you and Coloplast in 2014 and 2013.
A. When you say interaction -- I believe that I did go to find out more about their Y-mesh --
Q. Okay.
A. -- Restorelle.
Q. But you didn't --
A. I think --
Q. -- act as a consultant --
A. I think --
Q. -- for them?
A. But I'm not a consultant.
Q. Sure.
A. Nope. No --
Q. All right. So two --
A. -- payment --
Q. -- thousand -- 2013, 2014 you go to Coloplast-sponsored events to check out some of their products, specifically Y-mesh; correct?
A. That is correct.
Q. 2015 and 2016, you have some interactions

with Boston Scientific, on mesh -- a company that manufactures transvaginal mesh devices.

What were your --

A. They also had a Y-mesh too that I wanted to go learn more about.

Q. Okay. And Y-mesh is generally implanted abdominally; correct?

A. The Y-mesh is utilized for abdominal sacrocolpopexy. That is correct.

Q. And because I have a hard time saying that word, the ASC procedure, do you consider that the gold standard for treatment of pelvic organ prolapse?

A. Despite doing a lot of it now, I do not.

Q. Okay. Is that your primary surgical choice when you treat a patient who suffers from pelvic organ prolapse?

A. The indication for that surgery in the United States is apical prolapse. If a patient has apical prolapse and they meet the criteria and stratification, risk-benefit ratio, and it's the appropriate surgery for that particular patient, taking into consideration all aspects of that patient and their desire for future life, if it is all correct and it represents a true benefit, that

is what they will be offered.

Q. For apical prolapse, the primary surgical technique that you currently use is the ASC; correct?

A. It is but one tool in my armamentarium.

Q. Is it the primary one or not? That's what --

A. I don't --

Q. -- I'm asking.

A. -- think that it's -- I wouldn't say it's my primary.

Q. So you don't use the ASC more than any other surgical choice for apical prolapse is what you're telling me?

A. On review of -- of my personal performance over the last 3 years, I am sure I have done more abdominal sacrocolpopexy than other apical suspension native tissue repairs.

Q. Right. What's your go-to surgery or your primary surgery for rectocele?

A. I have to take -- I am a firm believer that you have to look at the entire POP-Q to see if there's any impingement upon the anterior, posterior, or apical. I have to see about -- I don't really truly believe that the -- isolated

defects exist. If this was truly an isolated posterior defect, then that patient would get a transvaginal native tissue site-specific repair reconstitution of the rectovaginal septum without any type of graft augmentation placed transvaginally.

Q. Is it fair to say that you currently don't use any Ethicon prolapse mesh kits?

A. I do not use any transvaginal mesh.

Q. Whatsoever; correct?

A. At all. I also do not use any type of graft -- xenograft, allograft -- nothing.

Q. Nothing?

A. Nothing.

Q. All right. You talked about position statement earlier.

And is it safe for me to assume that you're familiar with the fact that medical bodies in your field put out position statements? You're aware of that; right?

A. Correct.

Q. Okay. And let me pull up the one I like to show. You're familiar with AUGS; correct?

A. The American Urogynecology Society. Correct, sir.

Q. Yeah.

Are you a member of AUGS?

A. I am a member of the American Urogynecology Society.

Q. Nice. And --

A. I go to the annual meeting maybe every 3 or 4 years.

Q. Okay.

A. I did go this past year to the AUGS update class. And I am on my way next week, Saturday and Sunday, to a AUGS masters class.

Q. Nice.

A. So I do utilize them. I think they do a good job in providing opportunities to people to further their education.

Q. And you're generally familiar that they release position statements on transvaginal mesh for the treatment of pelvic organ prolapse; correct?

A. They have released such data in conjunction with other organizations. That is correct, sir.

Q. Okay. I'm going to read you a couple statements from a AUGS, slash, ACOG 2017 position statement on pelvic organ prolapse mesh.

Are you ready?

A. I am ready.

Q. Okay. Underneath summary of recommendations and conclusions -- first off, what is ACOG?

A. The American College of Obstetrics and Gynecology, not to be confused by the American Board of Obstetrics and Gynecology.

Q. Okay.

A. ACOG is just an organization.

Q. So AUGS and ACOG in 2017, in their position statement on pelvic organ prolapse mesh, underneath summary of recommendations and conclusions state, The use of synthetic mesh or biologic grafts in transvaginal repair of posterior vaginal wall prolapse does not improve outcomes.

Do you --

A. Posterior wall.

Q. Do you agree with that statement?

A. I do not agree with that statement.

Q. You disagree with AUGS and ACOG's position statement from 2017?

A. The statement that you just read is but one of many --

Q. Yeah.

A. -- points that I do not agree with the American Urogynecology Society nor the American College of Obstetrics and Gynecology.

Q. Tell me if you agree or disagree with this statement from the position statement: The use of synthetic mesh or biologic grafts in POP surgery is associated with unique complications not seen in POP repair with native tissue?

A. When I read that for the first time I think my jaw hit the ground in the sense that of course there's a unique complication profile for graft augmentation in relation to native tissue repair. In native tissue repair, you have no graft matrix, whatever it may be. There's no foreign body there. Even though you get suture erosion if you use a permanent -- but I'm not even going to go there. And you'll probably say, Strike that. But whatever. I don't know why they would feel the need to release a statement like that.

Q. You -- I get the feeling you kind of think it's a nothing statement. It's an obvious statement. Why would they say that? Is that -- am I feeling you there, or am I way off-base?

A. I look for guidance in how to practice from organizations that represent a larger body of knowledge --

Q. Right.

A. -- and is within myself. And I expect them to do a -- better guidance.

Q. And there's -- to you, there's nothing profound in -- in that -- or guiding in someone stating that there are complications unique to using mesh in pelvic organ prolapse surgery; correct?

A. I think that there's nothing unique about that statement, and that is common knowledge for anyone that puts themselves out there as a pelvic floor surgeon.

Q. That there's complications unique to the use of transvaginal mesh; correct?

A. I think that there is an -- I think there's inherent specific unique complications to any type of surgery that one does. One has to understand what they're doing. I don't need the American Urogynecology Society or the American College to point that out to me --

Q. Right.

A. -- at this phase of my career.

Q. Right. You don't need guidance on that there is -- there are unique complications associated with transvaginal mesh; right?

A. If you would like for me to say that transvaginal mesh in the form of certain complications are unique to graft augmented surgery, depending on which complication that you allude to, I would have to either say yes or no, depending on which parameter. And I would leave that to you to ask me.

Q. Mesh erosion?

A. If you don't have any mesh, you're not going to get an erosion unless you're using a permanent suture. If you use any type of foreign body, you can definitely have an erosion.

Q. How about the inability to remove -- to safely remove the entirety of the mesh?

A. Out of all of the questions that you have asked me today, that is the most -- I bet you I could utilize up all the remaining hours of today and continue talking until tomorrow about that topic.

How would you like me to answer that question, sir?

MR. WALKER:

Don't take all day.

BY MR. JONES:

Q. Yeah. I mean, I kind of just want you to answer the question that I just asked you, which is whether that's unique, whether that complication is unique to the use of transvaginal mesh, the fact that if complications do arise, that you can't ever freaking get this thing out of a woman's body entirely and safely?

MR. WALKER:

Object to form.

THE WITNESS:

I -- I -- and I'm not trying to be cute or . . . I don't know if we have decided as a collective of experts should the mesh in -- in block entirety be removed. I don't know that answer.

BY MR. JONES:

Q. Okay. And that's a different answer to the question I'm asking.

A. Give me one more shot.

Q. I'll try. All right.

We're focusing on whether this is a complication unique to the use of transvaginal mesh. That's the context that we're talking

about. And I'm asking you --

A. A complication has been encountered that is pushing a well-trained, educated, experienced pelvic surgeon to decide to remove the mesh?

Q. First off --

A. And you're saying that that person has to remove all of it?

Q. First off, removal of mesh or revision of mesh is a complication unique to using mesh; correct? You give me that?

A. I revise native tissue repair. I've had to go back and redo it.

Q. Removing mesh is unique to the use of mesh? Don't make this overcomplicated.

A. I'm not trying to.

Q. You seem like it.

A. This has been fun. I'm not trying to annoy anyone.

I can definitely tell you this: If there is a permanent mesh and it -- and it has eroded and it has to come out or part of it has to come out or you have to revise it, yes, because it's still present. And if that is what is causing the specific spectrum of symptoms, then yes, I grant you. You will take it out, but I do not know if

you need to take it all out.

Q. And my question isn't a discussion of whether you think it's appropriate to take it all out or whether another physician thinks, Shoot, Do we take out all we can because it's causing problems, or do we leave a little chunk in there to see what happens with the rest of it. That's not the question.

The question --

A. Okay.

Q. -- is: If a doctor makes the decision, This mesh needs to come out of this patient's body because it's in the best interest of this woman, in some patients, you will agree with me, that you can never safely and entirely remove all of the mesh from the patient's body?

MR. WALKER:

Object to form.

THE WITNESS:

I cannot say that. You're saying all patients. I --

BY MR. JONES:

Q. No. I just said "in some patients." If you listened, I said --

A. I'm sorry.

Q. -- "in some patients."

A. It depends on the practitioner. I definitely think that certain practitioners because of more skill attained through innate ability, knowledge, drive for perfection, maybe they have the skill set. I -- when I have had mesh complication from other providers, if I did not believe that I could handle the surgery, I have passed it on. That has happened a handful of my time, that I didn't think that I could safely do that. Those patients would not have existed if there was not a permanent graft in there. So if -- and -- so I'm just trying to make amends with you maybe in saying yes, those were certain permanent graft implants placed in people, and I felt that to safely remove it all I did not have the skill set and I passed that on.

Q. Okay. I believe that does help -- help me; so I appreciate that answer. All right.

I want to read -- read through a few more of these statements in AUGS, which I bet you'll probably disagree with. But I -- I've got three more that I want to read, and then we'll be done with that.

MR. WALKER:

And Nate, when you're done with that, can we take a break?

MR. JONES:

Yeah. Yeah. All right. So we'll get through these statements in AUGS.

BY MR. JONES:

Q. The use of synthetic mesh or biologic grafts in transvaginal repair of posterior vaginal wall prolapse does not improve outcomes. In addition, there are increased complications; e.g., mesh exposure associated with placement of mesh through a posterior vaginal wall incision.

Do you agree with that or disagree?

A. They're saying that there's a unique set of complications possible by placing the graft permanent or xenograft. And -- and yes, I could say that I agree with that. That is a distinct possibility.

Q. Okay. The next statement: Thus, synthetic mesh or biologic grafts should not be placed routinely through posterior vaginal wall incisions to correct POP for primary repair of posterior vaginal wall prolapse?

A. They're saying do not use a graft augmentation for the first time that you're going

to go to repair. So what they're advocating is: Go do a surgery that you know is going to probably have a 30 to 40 percent chance of failure so the patient comes back and makes your second revision harder. So I don't really understand that concept, and I don't agree with it.

Q. You don't agree --

A. I think you have to -- you have to -- you have to individual -- individualize care.

Q. And now we're talking about interior vaginal repair. Polypropylene mesh augmentation is associated with higher rates of complications compared with native tissue vaginal prolapse repair.

You agree or disagree?

A. I disagree.

MR. JONES:

All right. Let's take that break.

(Brief recess was taken.)

BY MR. JONES:

Q. All right, Doctor. We took a short break.

Are you now ready to proceed?

A. Yes, sir.

Q. Good deal. All right.

Besides the Prosima, what other pelvic

organ prolapse mesh kits did you use?

A. I can definitely say that I used them all.

Q. Used them all?

A. At least all -- at least one to several times each.

Q. Okay. Based on your experience in using every single transvaginal mesh product for treatment of pelvic -- pelvic organ prolapse at least once, are there any specific things that stand out to you about the safety and performance of any of those particular mesh devices?

A. I came into my fellowship before the advent of the vaginal mesh kits, transvaginal mesh kits. And in fact, it was referenced in a paper that I did. It was on my CV. I'm very proud of it.

Q. Nice.

A. Where we fashioned two pieces of Gynemesh and delivered it utilizing the Capio device. I'm telling you that so that you don't -- I'm not trying to be boastful. I'm trying to tell you that violation of the sacrospinous ligament neurovascular complex is something that all of these mesh kits have in common. Prosima, and Prosima only, is the one that did not violate that

structure. So none of these kits satisfied my curiosity, if you would like to say, or my approach to operating safely in a very challenging piece of anatomy, transvaginally that is.

Q. What about the -- I understand the surgical approach didn't fascinate you or meet your standards.

But what about the character -- characteristics of any of those mesh products? Does anything stand out to you as far as one mesh device, the actual mesh portion being softer or lighter or more pliable or one being stiff, heavy, rigid? Anything like that stand out to you, Doctor?

A. Out of all of them, I was -- I was intrigued at the time what became Restorelle, was Empathy.

Q. Sure.

A. I thought they had a winner back then. It was too expensive. I couldn't get the hospitals to buy it; so I did not have access to it, sir.

Q. And Restorelle is a -- is a light, soft mesh; correct?

A. It is. It's by Coloplast now, but it was bought by -- by them.

Q. Yeah.

A. Okay.

Q. Right on. I think you said Empathy and then Coloplast.

What did you do after you graduated undergrad?

A. I tried to get into medical school. Then I did -- went to a master's degree. If you look at the CV, it says certificate of anatomy. That was a program at the St. Louis University School of Medicine. I went to undergrad at St. Louis University.

Q. Yeah.

A. So the program was to give heavily motivated people the opportunity to maybe take the anatomical classes of the first year of medical students and see how they do. But the problem with that program was when you let 40 motivated kids in, we all did well. So they threw a MCAT recommendation again. And I -- and I've always had a hard time with that test. So then I went off and worked a while, and then I went back and got my master's in molecular biology, protein conformation dynamics, tried to get into medical school again. Despite a 4.0, I couldn't do well

on the MCAT. Worked at a high volume PCR lab doing protein -- doing viral load analysis.

MR. WALKER:

Hey, Nate, I'm sorry to do this. Can -- can we go off the record for just a minute?

(There is an off-the-record discussion.)

(Brief recess was taken.)

BY MR. JONES:

Q. All right. Here's what I want to ask you about and focus on, is the work that you did after undergrad. Where'd you work?

A. Consolidated Laboratory Services.

Q. Okay. What's this DuPont work stuff? Did you work there, or is that --

A. No. That's -- so at the time all the antiretroviral medications were coming out. And PCR at the time --

Q. Okay.

A. You want me to really expand on that or . . .

Q. Yeah. Give me like the 2- or 3-minute version. I told Jordan we'd be done by 2:00; so expand but don't expand that much. That's a good lawyer answer for you, by the way.

A. So Hoffmann-La Roche had a kit. So you -- HIV replicates, and you have viral load: hundred thousand copies, 50,000 copies, zero copies. The more copies, the sicker you are. I give you a pill that is an antiretro, and then we can modulate how fast and how low we can get it. So that's what we did, DuPont Merck DMP 266. I can't even remember what it --

Q. Sure.

A. -- turned out to be. It's one of many. So we did high volume PCR analysis, which at the time was pretty cutting edge.

Q. Cool. All right.

And then you talked about -- you had some difficulties getting into medical school; correct?

A. That's correct.

Q. And eventually --

A. In the United States.

Q. In the United States.

And eventually you attended medical school outside of the United States; correct?

A. That is correct.

Q. And you attended medical school outside of the United States because of your difficulties getting accepted into a medical school inside the

United States; correct?

A. That is correct. There was 132 medical schools at the time. There's many more now. But yes, that is correct.

Q. And you --

A. I think I hold the distinction of being rejected by each one not once but twice. I have a binder somewhere with it.

Q. You got to get rid of that binder, man.

A. Oh, no. No. No.

Q. Just --

A. It's that --

Q. -- move on.

A. -- other chip on my other shoulder.

Q. I get it, but you got to move on. You know, you got to . . . All right. So there will just be about a few more questions on this subject, and then I'll move on.

Is it fair to say that you were not accepted into any medical school inside the United States?

A. Not once but twice. Yes. I -- there were many applications. I can't keep track. I might say that in jest. But regardless, there was no MCAT policy at Dominica Ross University School of

Medicine. I had friends that went, and they were succeeding in their dreams. And my dream was always to be a physician; so I said screw it and I went down there.

Q. You did it?

A. We did it.

Q. And the medical school you attended is located -- or was located in the --

A. On the island of Dominica until the island of Dominica got wiped out last year. I think they're in the process of transferring over to Barbados.

Q. Okay. And that medical school is not accredited in the United States; correct?

A. No.

But whatever the -- the certification allows you to take out American student loans for that in paperwork; so they have certain credentials that allows them to do that. And then the resident -- the graduates are allowed to take the full gambit [sic] United States medical license examining 1, 2, all of it. So it's the same thing. So you're allowed to go.

Q. I'm going to just ask it again so I can just get the -- the answer to it.

But the medical school you attended in -- on the island of Dominica was not accredited in the United States; correct?

A. No. It was not a United States medical school.

Q. And it was -- its accreditation came from the Government of Dominica; correct?

A. That is correct.

Q. Okay. Are you familiar with the Journal -- JAMA or JAMA, Journal of American Medical Association? Are you familiar with JAMA?

A. I -- I get a e-mail from them at least a day or -- every day.

Q. Is it safe to say that the American Medical Association's medical journal that they put out, JAMA, is reliable among doctors?

A. I think it is one of many journals that people read.

Q. It -- it's a peer-reviewed medical journal; right?

A. Uh-huh.

Q. It goes through a peer-review medical process, where doctors and the editing board review the materials submitted to the journal; correct?

A. That is correct.
Q. And while you may not agree with everything that JAMA produces, you do accept that it's a reliable peer-reviewed medical journal in -- amongst doctors that they refer to; correct?
A. I do believe people read it. I don't know its impact score; so I don't know how prestigious it is. So -- and that -- isn't that the . . .
Q. Yeah. I'm not asking whether --
A. Okay.
Q. -- it's the best or the worst. I'm saying it's reliable?
A. It's an article.
Q. Okay. It's an -- it's a peer-reviewed medical journal that's reliable among doctors; correct?
A. Uh-huh.
Q. Okay.
A. That is correct.
Q. Has any transvaginal mesh company before working on this case ever asked you to work as an expert?
A. Any manufacturer of a transvaginal mesh kit ask me to work on their behalf?
Q. Uh-huh.

A. In two thousand and -- going from my fellowship to this point?

Q. Right.

A. I was asked. Yes. I was asked to -- to work on behalf of pretty much all of them, and I did not.

Q. You were asked to act as a expert witness for --

A. Oh. Expert witness. I thought expert utilizing their products. They always said, If you use our products, you can become a teacher, and then you could do this and X, Y, Z. No. It's --

MR. WALKER:

Your -- your question is in the context of litigation?

MR. JONES:

Yeah. In the context --

THE WITNESS:

Well, then no.

MR. JONES:

-- of litigation.

THE WITNESS:

No. No one has --

BY MR. JONES:

Q. Prior to your work performed on -- in authoring this Prosima report, a transvaginal mesh -- transvaginal mesh company has never asked you to work as an expert in -- in litigation context?

A. That is correct.

Q. Has any medical device company ever asked you before your work done in this case to exam -- to -- to help them draft the product label associated with their medical device?

A. No.

Q. Has --

A. No.

Q. -- any medical device company ever asked you prior to your work on this case to review the adequacy of their product label associated with their medical device?

A. No, sir.

Q. Has any medical device company prior to this case ever asked you to -- to review the appropriateness of the warnings and adverse events statements associated with a medical device product?

A. No, sir.

Q. Have you ever -- are you familiar with --

are you familiar with the industry standards that govern what information as it relates to the safety of medical device is required to be in -- in a product label?

A. No.

Q. Are you familiar with the FDA guidelines?

A. In regards to what, if I may ask?

Q. On what information should be included in a product label as it relates to the safety performance of that device.

A. No. I -- I've never reviewed the mandates from the Food and Drug Administration and how that governs --

Q. Have you --

A. -- labeling.

Q. Have you reviewed internal documents from Ethicon that provide guidance and standards for what information must be included in a product label as it relates to the safety and performance of a medical device?

A. I can't recall reading something like that.

Q. Are you familiar with failure modes and effects analysis?

A. Failure mode analysis?

Q. Yeah. FMEAs.

A. I think I was more familiar with it from my fascination with aviation, where certain components of aircraft would be -- or even automobile, to see if it -- to -- to see failure levels on even piping in one's home. So I think that -- I knew that -- so I think I was -- I didn't see a number in all of the documents that I reviewed. In like how many of these cases would fail, I didn't see that. And I was intrigued to see if anyone knew or had a model of what reality would turn out to be.

Q. Yeah.

A. We had -- you had projection, but I would have liked -- I think that would have been a fascinating number to see.

Q. We talked earlier. You're not a polymer chemist; right?

A. I had to take organic chemistry a couple of times. It was a hard class.

Q. Yeah.

You're not a polymer chemist, though; right?

A. Absolutely not.

Q. And you don't -- as far as the design of

the Prosima, which to me includes the VSD and the mesh -- we talked about the VSD and the -- the uniqueness and -- and novel approach and some of the reasons why that was fascinating to you, but others as well.

But as far as the mesh, the mesh used in the Prosima device was not unique or novel; correct?

MR. WALKER:

Object to --

THE WITNESS:

No.

MR. WALKER:

-- form.

BY MR. JONES:

Q. Okay. And --

A. I do not think that it was unique to the Prosima device.

Q. And -- and that same mesh was used in the Prolift kit; correct?

A. I believe so. I'm not nearly as familiar with Prolift as I am with Prosima, sir.

Q. And as far as the mesh, you don't have any opportunity as a physician -- other than what we talked about with Restorelle earlier, you didn't

have any opportunity to tell a company like, Hey, Ethicon, hey, man, I really love this Prosima device, especially because of the VSD, In a way, that eliminates a lot of the -- the problematic surgical approaches with transvaginal mesh augmented prolapse repair, But I don't like the mesh you're using in this, so give me a different fucking mesh or -- or a different mesh.

A. Okay.

Q. You don't have that opportunity as a physician; correct?

MR. WALKER:

Object to form.

THE WITNESS:

I don't think that it's possible for me to ask a major corporation --

MR. JONES:

Right.

THE WITNESS:

-- in the United States: Build something for me.

MR. JONES:

Right.

THE WITNESS:

I wish I could.

BY MR. JONES:

Q. Right. And so you're left in a position as a physician to use the medical devices that the companies put out on the market; correct? And you -- correct?

A. That is correct.

Q. And you've never worked --

A. But I -- I was doing something similar before these kits came out; correct? So we accept that? I was putting mesh into human beings, Gynemesh.

Q. Gynemesh?

A. Into people.

Q. Gynemesh?

A. That's it, Gynemesh.

Q. Gynemesh is denser, stiffer, and heavier than Gynemesh -- Prolene soft; correct?

A. That is correct.

Q. Okay. And are you familiar with Ultrapro mesh?

A. Ultrapro is Prolene polypropylene with I think monocryl --

Q. Partially absorbable mesh; correct?

A. Yeah.

Q. And the partially -- partially absorbable

mesh is lighter and softer than a mesh like Prolene soft; correct?

A. It is.

Q. Is there -- did -- did you ever do slings?

A. Mid-urethral slings?

Q. Yeah.

A. It's part of the armamentarium --

Q. Is -- is --

A. -- to deal with SUI.

Q. Is there any reason why a mesh like Prolene soft would not work with -- in a mid-urethral sling?

MR. WALKER:

Object to form.

THE WITNESS:

I don't know if that's been studied. I guess if you are able to attach the trocar needles to a piece of Gyne, I think it could be done.

BY MR. JONES:

Q. Okay. Back to my original line of questioning.

So you're not -- you've never been involved with a medical corporation in helping them decide which particular mesh they're going to

use in one of their devices; correct?

A. I've never reached that level of position to be able to dictate something like that.

Q. And we talked about this earlier.

But some of the important mesh characteristics as it relates to safety of the mesh included stiffness, porosity, density, and weight, among others; correct?

A. Among others, yeah. Uh-huh.

Q. Is it fair that you don't consider yourself an expert in the mesh selection process as it relates to stiffness, porosity, density, and weight when a medical device company is selecting which mesh to use in their medical device?

A. I never had any input into any of those parameters when the manufacturer of any of these different types of grafts -- that is correct.

Q. And along the same lines, is it safe for me to assume that you don't consider yourself an expert in the warnings information that are included in the product label?

A. I don't think that I was ever in a position to dictate what should or should not be in a warning label. But I do believe that it's my responsibility to make other people aware if there

were problems with certain applications of certain technologies, ergo in a paper, and I think I did that in the complications of transvaginal mesh.

Q. But because -- well, let me ask it this way: Based on your experience and -- and the things we talked about earlier, like industry standards and FDA guidelines and whether you yourself had ever been -- worked on a product label, you don't consider yourself an expert in that field; correct?

A. But why would I? I am -- I am the -- I am the tool. I am the delivery --

Q. Right.

A. I am the delivery --

Q. Right.

A. -- device.

Q. Right. You are -- and I want to be fair. So, I mean, you're the physician, and so you're assessing the -- the patient and the risk and potential benefits of the medical device that you're offering your patient; correct?

A. Yes. I am the -- I am the implementer.

Q. You're the implementer.

And there are some things that -- that aren't your responsibility but are the medical

device company's responsibility. Fair?

A. At the end of the day, all of that responsibility on what I'm doing with that patient is my responsibility.

Q. Right.

A. I don't have to --

Q. Right.

A. -- put that graft in. I don't even have to do surgery on that person. I would have to say management of each and individual patient is my responsibility.

Q. You're not -- and -- and I get that.

Back to the warnings and labels, you're not -- that's not what you do every day? You don't sit around and write product labels every day? The --

A. I certainly --

Q. -- companies do, though?

A. I certainly am not Ethicon. I was never directly an employee. You don't see a -- so I don't understand that. That is not my position in life.

Q. Right.

A. My position in life is to execute and deliver health care.

Q. Right. Right. And because of that, you're an expert in -- in delivering health care to your patients; correct? That's fair?

A. That is fair.

Q. You don't consider yourself an expert in what warning statements need to be in a product label for a medical device, though. Is that fair?

A. I've never been put in a capacity to do that.

Q. Okay. We talked earlier about being sent -- oh, man, I only got ten more minutes -- about being sent patients -- having patients referred to you who will have complications after having transvaginal mesh placed inside their body; correct?

Let me ask you: Do you have patients referred to you who have suffered from complications who have had transvaginal mesh previous placed in -- inside their bodies?

A. Not only do I get such patients referred by other physicians, other members of the community, I have been solicited by members of the legal community who had promised to send me inordinate amounts of patients to remove mesh.

Q. That's not good.

A. That is not good.
Q. And just so --
A. I actually reported it to the --
Q. Good.
A. -- medical director of my hospital.
Q. I'm glad you did.
And -- and just so we're clear, I never did that, did I?
A. No, sir. You --
Q. I never --
A. -- did not.
Q. Okay. Jordan --
A. You did not.
Q. -- didn't do that either? But -- no. Okay.
So you do get patients referred to you by other physicians in other --
A. And other patients.
Q. -- and other patients who suffer from mesh complications. Is that fair?
A. That is correct.
Q. And what part of your -- percentage of your current clinical practice relates to treating women who suffer from mesh complications?
A. When you say "mesh complications," these

are people that perceive that their issues relate to a previous implant done by an outside provider. If I myself am the implanting physician, I always tell my patients that they and I are bonded; so please always let me know. But otherwise, what you're saying is -- yes. I evaluate them completely, and we try to come up with a plan to help them address their issues.

Q. And you've treated women who have had Ethicon transvaginal mesh products implanted in them and who now suffer from complications; correct?

MR. WALKER:

Object to form.

THE WITNESS:

I have dealt with a full component of all of the transvaginal kits, from Elevate to Apogee, Perigee, Pinnacles, homegrown, Prolift. I --

BY MR. JONES:

Q. Prolift is a -- is a transvaginal mesh device that was formerly marketed by Ethicon; correct?

A. That is correct.

And I also manage sacrocolpopexy

complications.

Q. How about Prosima? Have you had any Prosima patients?

A. I have not personally come across any Prosima complication in the last five -- what year is this? 2018. 2011 . . . So in the last 7 years, no Prosima implant patient has been referred to me, nor have I heard of any Prosima patient of mine within the community going to another provider for management of whatever issue that they were having.

Q. And Prosima was only available to surgeons for a couple years; correct?

A. I think it was the -- some type of corporate decision was made to no longer make it, and I think it dissipated. Because I think that the packaging only had a 4-year shelf life. So I think that when it was introduced maybe in 2009, I think in -- then it was no longer manufactured. I think they stopped making it. That's all they did. And they -- in two thousand and, I think twelve.

Q. Yeah. So they launched the device in December 2009, and then in 2012, they -- they ceased selling the device or making the device?

A. I think they stopped manufacturing the device, and I think if there was still product somewhere you could get your hands on it.

Q. So there's -- so there is a little bit more than a 2-year time period for when Ethicon was actively marketing this device; correct?

A. Yes.

Q. Okay.

A. They were actively --

Q. And --

A. -- marketing it.

Q. And based on your consultant work with Ethicon, you know that this wasn't an entirely successful product for Ethicon; correct?

MR. WALKER:

Object to form.

THE WITNESS:

I thought that it was an extremely successful product.

BY MR. JONES:

Q. Did you -- did you ever -- did you ever -- were you ever made aware of how many total Prosima devices were actually ever used in the United States?

A. For some odd reason, a number between four

and 6,000.

Q. Okay. That's what you think?

A. I think.

Q. Okay.

A. Am I allowed to ask what the number is, if you know?

Q. You can ask Jordan.

THE WITNESS:

Am I allowed to ask you how many that is -- was? What? You won't tell me? Okay. I --

MR. JONES:

Yeah.

THE WITNESS:

-- don't know.

MR. JONES:

He probably won't tell you.

BY MR. JONES:

Q. All right. So we've got four to 6,000 women out there in the United States with a Prosima device. That's it; correct?

A. Maybe more if I'm incorrect.

Q. Okay. But if we're assuming you're correct, there's anywhere from four to 6,000 women in total who have received the Prosima device

inside the United States --

A. Uh-huh.

Q. -- correct -- if you're correct?

A. If I am. I don't know if it's just the United States or worldwide. I -- because it was available worldwide, not just in the United States.

Q. All right. I think the way I'm going to finish up is I'm going to ask you about some specific -- some specific internal documents that are pretty noteworthy, where employees inside of Ethicon are discussing Prosima and they're saying things about the device that stand out for sure. I'm pulling up work product from 4 years ago from a Prosima trial. And I'm watching my computer load it right now.

MR. WALKER:

That -- that wouldn't be the Cavness trial?

MR. JONES:

It would be.

MR. WALKER:

How about that?

MR. JONES:

It would be.

MR. WALKER:

Were you at that trial site?

MR. JONES:

I was. I was -- I was a -- the person they just keep locked up in the closet the whole time and never let come out, just feed to keep you alive so you can continue to work. That's about it.

MR. WALKER:

A war room rat --

MR. JONES:

Yeah.

MR. WALKER:

-- basically.

MR. JONES:

Great experience, though.

BY MR. JONES:

Q. Yeah. So what I'm going to do here, Doctor, I'm going to just pick out some of the internal documents that discuss Prosima. Most of them are from medical directors, some of which we talked about before, like Aaron Kirkemo.

MR. WALKER:

Are you going to let him look at them on -- on your screen?

MR. JONES:

I mean, that means we're going to be here for a lot longer. But I'll -- I'll probably -- if I can pull them up, I'll -- I'll let you look at them as long as it doesn't take a super long time. Some may just jump out. Some may be like: Oh, yeah, I remember that one.

BY MR. JONES:

Q. Are you aware that Ethicon began working on a Prosima +M device, where they were going to use Ultrapro in the Prosima?

MR. WALKER:

Object to form.

THE WITNESS:

That, I do not know.

MR. JONES:

Loading up.

BY MR. JONES:

Q. Okay. Are you familiar with Dr. Vincent Lucente?

A. I am.

Q. You are? And are you aware -- how -- how are you aware of Dr. Vincent Lucente?

A. I think I have nothing but admiration and

respect for Dr. Lucente. His 2005 AUGS conference and -- I knew that I wanted to be a urogynecologist more than anything. And he was Vince Lucente.

Q. Yeah.

A. Okay. He actually mentored me, helped me. He let me talk with the correct people. He introduced me around. And to this day, I have nothing but admiration and respect for him as a human being. I don't think he's ever forgiven me for never using Prolift or some of his other products, but that does not mean -- we're very collegial.

Q. Did you review the Ethicon internal document where Dr. Lucente calls Prosima a reckless product?

MR. WALKER:

Object to form.

THE WITNESS:

I definitely did not see that document because it would have stuck out in it and I would have most likely called him on my cell and said, You're incorrect.

BY MR. JONES:

Q. You didn't see that document, though;

correct?

A. I did not see that document.

Q. Did you go to the 2009 Gynecare summit in Florida at the Gaylord Palms Resort & Convention Hotel, by chance?

A. Is that where they filmed Back to the Future? Is that the one? I'm not trying to --

Q. Got me there, man.

A. I -- I think I was -- I've been to Florida a couple of times on . . . You know, so I think one was that place, which was a big conference.

Q. Yeah.

A. That was the big thing. So I don't know where the Gaylord Hotel . . .

Q. Okay.

A. Is that . . .

Q. Yeah. I -- I don't know where it is either. Maybe I can Google it real quick.

But anyways, you -- you -- you went to a few Ethicon-sponsored summits in Florida; correct?

A. Correct.

Q. And do you recall there being presentations on Prosima?

A. Yeah. I think I do. I can't really remember.

Q. And do you remember specifically going to this hotel? The hotel is located in Orlando. So perhaps that was Back to the Future, some of that stuff was involved. But I -- I'm going to ask you about some reports from that summit where there was a Prosima presentation given and ask if you've looked at these documents. And again, these are ones that you either saw them or you didn't because they say powerful things, you know.

The feedback was from the 2009 Gynecare summit after they gave a presentation on Prosima. The feedback includes: Big mistake, Don't do it, Did not make sense, Worried that the risk-benefit ratio could produce a backlash.

A. I think Aaron Kirkemo --

MR. WALKER:

Object to form.

THE WITNESS:

-- wrote that.

MR. WALKER:

Object to form.

THE WITNESS:

Did he not?

BY MR. JONES:

Q. Did he?

A. If I can come over to your computer screen. And if I --

Q. Yeah. It's not --

A. If it is --

Q. -- going to help you.

A. If it is Kirkemo, then obviously I'm an ethical human being. Because I could pull that document out of the gigabytes of stuff that I've looked though.

Q. So you do --

A. Because that's a powerful statement.

Q. Powerful.

And you do recall reading statements from Ethicon's medical director, Aaron -- Aaron Kirkemo, telling the company: Don't launch the Prosima device?

MR. WALKER:

Object to form.

THE WITNESS:

I don't remember the exact words. But I remember this long e-mail, and he -- I don't know why he dragged BPH into it and uroflow studies. You're smiling because that's a pretty good damn memory that I could do this; right? Because that's how

much I disagree with him.

BY MR. JONES:

Q. Okay. But you -- you generally recall seeing documents detailing the negative feedback following the 2009 conference that speak to potentially Aaron Kirkemo's comments; right?

A. I definitely --

MR. WALKER:

Object to form.

THE WITNESS:

-- can say to this out of all of the documents that I read: I read many positive as well as negative comments regarding Prosima.

BY MR. JONES:

Q. Did you review the sales brochures associated with the Prosima device?

A. Of course I have reviewed them, because I think they were distributed to patients and I want to make sure that it did its job of conveying messages to patients.

Q. Were there any -- in your review of the brochures associated with the Prosima device that Ethicon used, did you notice any statements that appeared to you to be misleading?

MR. WALKER:

Object to form.

THE WITNESS:

I -- if I -- upon -- I would have to review the information once again. But I don't think that I had a problem with it. If I had -- if I utilized the -- it, I don't think that it would have represented any type of misinformation. But I think that such a pamphlet is just but one component of truly educating a patient so that they could make proper decisions of their health care.

BY MR. JONES:

Q. Do you know who Martin -- Dr. Martin Weisberg is?

A. I do not know who Dr. Martin Weisberg is.

Q. Did you stop using Prosima before or after Ethicon ceased marketing the device?

A. I think that it -- cessation of -- of Prosima utilization occurred in 2011; so I think whenever they actively stopped marketing it. I don't think that has a bearing as -- you know, if that lines up with what -- in 2011, then that was it.

Q. Okay. I'm -- I'm just asking.

Did you stop using it because Ethicon stopped selling it, or did you stop using it before Ethicon stopped selling it?

A. I stopped using it before Ethicon stopped selling it.

Q. Okay. Why was that?

A. Because I wasn't really practicing at the time.

Q. Okay.

A. And by the time that I restarted my own practice at East Jefferson Hospital, I don't think the environment was conducive to utilizing transvaginal mesh at that time. Because that was after the FDA notice.

Q. Sure.

MR. JONES:

Those are all the questions I have. Thanks for your time today, Doctor.

THE WITNESS:

Thank you, sir.

MR. WALKER:

I have just a couple of follow-up questions.

BY MR. WALKER:

Q. Doctor, do you remember being asked some questions about the AUGS position statement?

A. Yes.

Q. And specifically you were asked questions about the AUGS statement regarding the efficacy of mesh in the posterior compartment.

Do you remember that?

A. Yes.

Q. Why do you disagree with AUGS' statement regarding the efficacy of mesh augmentation in the posterior compartment?

A. In my -- I simply did not see such a degradation and repair. I did not -- and I truly felt that a native tissue repair in posterior compartment is basically a nonfunctional approach, that graft augmentation in the posterior compartment is vital to a successful repair if done appropriately.

Q. And you -- you say "if done appropriately."

From your experience and your review of the literature, if a skilled surgeon is placing a posterior mesh, is that likely to result in a greater benefit to the patient than a native tissue repair?

A. I believe graft augmentation delivered to the appropriate surgical plane utilizing the appropriate fixation points represents a true and utter benefit to the patient. Yes.

Q. I made a note early in the deposition. You were asked some questions about your professional education involvement with Ethicon and the numerous cadaver studies that you participated in.

Why is the study of cadavers important to your education and professional development?

A. The cadavers were not donated to me as a thank you or anything from Ethicon. These cadavers were provided so that surgeons -- after didactics and education, mentoring by more experienced surgeons, passes were done. And then passes were done in nondissected and dissected portions of these cadavers so people could learn how to do these procedures properly. When everything was said and done and everybody was going to the dinner or going back home, I was able to stay and really take inventory of deep dissection of these structures. So I found it to be invaluable. So . . . before these were then properly dealt with.

Q. You were asked a number of questions regarding the stiffness of mesh, density, pore size.

Do you recall those questions?

A. I do.

Q. And, Doctor, you would agree that you are here today in part because you are holding yourself out as an expert in the biocompatibility of mesh, specifically the Prosima mesh product; correct?

A. That is correct. I hold myself as a expert when it comes to Prosima and the application of its technology.

Q. And that would include the -- the mesh in Prosima and the construction of that mesh; correct?

A. I hold --

MR. JONES:

Objection.

THE WITNESS:

-- myself in knowing a substantial amount of knowledge based on all my education, self-study, experience with all the different platforms, and these cadaveric dissections.

BY MR. WALKER:

Q. And, Doctor, you recall you were asked some questions about the warnings associated with product labeling.

Do you recall --

A. Uh-huh.

Q. -- that?

As a pelvic floor surgeon, do you agree that you are an expert in assessing the potential risks and complications associated with pelvic floor surgery?

MR. JONES:

Another objection.

THE WITNESS:

I completely hold myself in a position to judge the application of technology when it comes to the realm of pelvic surgery. That is correct.

BY MR. WALKER:

Q. And that would include understanding and being knowledgeable about the potential adverse events that could happen following a prolapse repair surgery, for example?

MR. JONES:

Objection.

THE WITNESS:

I think any ethical surgeon who takes a human being to the operating room with the hopes of making them better learns from each and every individual case. Now I'm not trying to sound like a cheerleader. So any type of positive should be noted, and more importantly, any type of negative should be noted. And you take and you learn from each.

Going back to the cadavers. Learning that anatomy in real life, I have to stress once again the invaluable nature. Because transvaginal surgery is not so easy. You're operating through very confined spaces. And I'm not trying to say anything with regard to certain skills. But really being able to open up that -- these very confined spaces was extremely beneficial in learning how these grafts would work, where they were going, and also as a basis of further understanding as a professional developing in pelvic surgery. I don't know what else to say about that.

MR. WALKER:

That's all I have. Thank you for your time.

THE WITNESS:

All right. Thank you.

MR. JONES:

A few housecleaning issues.

Do you have any objection to me e-mailing the notice of deposition to the court reporter after the deposition? Unless you have a copy.

MR. WALKER:

I have a copy.

MR. JONES:

Easy. I would like to mark for the record the deposition notice as Exhibit No. 5.

(Exhibit No. 5 was marked for identification and attached hereto.)

MR. WALKER:

And you -- you didn't mark it. But if you want, I also have his CV. I don't know . . .

MR. JONES:

Let's do it. Exhibit 6 will be the

doctor's CV.

(Exhibit No. 6 was marked for identification and attached hereto.)

MR. JONES:

And then . . .

MR. WALKER:

And if you want to mark his report, I have that as well.

MR. JONES:

Yeah. And then the next exhibit -- because I already lost count -- Exhibit 7ish --

MR. WALKER:

I think it's 7.

MR. JONES:

-- will be the report of the doctor in this case. Just -- and then --

MR. WALKER:

That's just three copies of the same report.

MR. JONES:

Okay. And -- and then do you have any objection to me e-mailing for the record to the court reporter the -- the electronic copy of the report that

includes all like the -- the reliance list and the PowerPoint stuff?

MR. WALKER:

I -- I don't. I do have a hard copy of the slide deck that was attached to his report, if you want to go ahead and just mark the hard copy.

THE WITNESS:

I thought he gave -- you gave it to him already?

MR. JONES:

Yeah. You did.

MR. WALKER:

You already --

MR. JONES:

Did I mark it earlier? Whatever. If I --

MR. WALKER:

Okay.

MR. JONES:

-- marked it earlier, I marked it.

MR. WALKER:

Here (tenders document).

MR. JONES:

If not, I would like to add that to --

MR. WALKER:

But no objection.

MR. JONES:

-- Exhibit 7.

THE WITNESS:

I think you have it. Yeah.

MR. JONES:

I don't want to take it with me. So . . . All right. That's it. Thanks, guys.

MR. WALKER:

All right.

THE WITNESS:

Thank you, sir.

MR. WALKER:

We're off the record.

(The proceedings concluded at 2:18 p.m.)

C E R T I F I C A T E

This certification is valid only for a transcript accompanied by my original signature and original seal on this page.

I, AURORA M. PERRIEN, Registered Professional Reporter, Certified Court Reporter, in and for the State of Louisiana, as the officer before whom this testimony was taken, do hereby certify that AHMET BEDESTANI, M.D., after having been duly sworn by me upon the authority of R.S. 37:2554, did testify as hereinbefore set forth in the foregoing 118 pages; that this testimony was reported by me in the stenotype reporting method, was prepared and transcribed by me or under my personal direction and supervision, and is a true and correct transcript to the best of my ability and understanding; that the transcript has been prepared in compliance with transcript format guidelines required by statute or by rules of the board; and that I am informed about the complete arrangement, financial or otherwise, with the person or entity making arrangements for deposition services; that I have acted in compliance with the prohibition on contractual relationships, as defined by Louisiana Code of

Civil Procedure Article 1434 and in rules and advisory opinions of the board; that I have no actual knowledge of any prohibited employment or contractual relationship, direct or indirect, between a court reporting firm and any party litigant in this matter nor is there any such relationship between myself and a party litigant in this matter. I am not related to counsel or to the parties herein, nor am I otherwise interested in the outcome of this matter.

AURORA M. PERRIEN, CCR, RPR